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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 19424PC KATHRYN J. HOFMANN 7265 08/913,644 11/21/1997 08/27/2003 JOANNE M GIESSER **EXAMINER** MERCK & CO INC SALIMI, ALI REZA 126 EAST LINCOLN AVENUE PO BOX 2000 ART UNIT PAPER NUMBER RAHWAY, NJ 07065 1648 DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 08/913,644

Applicant(s)

\_\_\_\_

Hofmann et al

Examiner

A. R. SALMI

Art Unit 1648



•	The MAILING DATE of this communication appears of	on the cover s	heet with	the correspondence address		
	for Reply					
THE N	ORTENED STATUTORY PERIOD FOR REPLY IS SET MAILING DATE OF THIS COMMUNICATION.  sions of time may be available under the provisions of 37 CFR 1.136 (a). In r	_		_		
mailing	mailing date of this communication If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.					
- If NO p - Failure - Any rep	period for reply is specified above, the maximum statutory period will apply at to reply within the set or extended period for reply will, by statute, cause the oply received by the Office later than three months after the mailing date of the ply received by the Office later than three months after the mailing date of the ply received by the Office later than three months after the mailing date of the	and will expire SIX (6 he application to beco	6) MONTHS fro come ABANDO	rom the mailing date of this communication. ONED (35 U.S.C. § 133).		
Status				·		
1) 🗆	Responsive to communication(s) filed on			·		
2a) 🗌	This action is <b>FINAL</b> . 2b) ☐ This acti	tion is non-fine	al.	•		
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.					
	tion of Claims					
4) 💢	Claim(s) <u>1-20</u>			is/are pending in the application.		
4	4a) Of the above, claim(s)	<b>A</b>		is/are withdrawn from consideration.		
5) 🗆	Claim(s)			is/are allowed.		
6) 🗆	Claim(s)			is/are rejected.		
7) 🗆	Claim(s)			is/are objected to.		
8) 💢	Claims <u>1-20</u>	ar	e subject	to restriction and/or election requirement.		
Application Papers						
9) 🗆	The specification is objected to by the Examiner.					
10)	The drawing(s) filed on is/are	, a) 🗌 accept	ed or b)	$\square$ objected to by the Examiner.		
	Applicant may not request that any objection to the dr	Irawing(s) be h	eld in abev	yance. See 37 CFR 1.85(a).		
11)	The proposed drawing correction filed on	i <i>;</i>	s: a) □ a	pproved b) $\square$ disapproved by the Examiner.		
	If approved, corrected drawings are required in reply to	to this Office a	ction.			
12)	The oath or declaration is objected to by the Examin	iner.				
Priority	under 35 U.S.C. §§ 119 and 120					
13) 🗌	Acknowledgement is made of a claim for foreign pri	riority under 3	5 U.S.C.	§ 119(a)-(d) or (f).		
a)	☐ All b)☐ Some* c)☐ None of:					
	1. $\square$ Certified copies of the priority documents have	/e been receiv	ed.			
;	2. Certified copies of the priority documents have	e been receiv	ed in App	lication No		
	3. Copies of the certified copies of the priority do application from the International Burea	locuments have eau (PCT Rule 1	ve been red 17.2(a)).	eceived in this National Stage		
_	ee the attached detailed Office action for a list of the	·		•		
14) 🗀	Acknowledgement is made of a claim for domestic			ø		
a) ∟ 15\□	5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					
15) 🗀	Acknowledgement is made of a claim for domestic	priority unaer	35 U.S.C	2. §§ 120 and/or 121.		
Attachme		41 Interview 5	'(PTC	0-413) Paper No(s).		
		_		P413) Paper No(s)		
_		6) X Other: Se	•			
				, CH · r		

Application/Control Number: 08/913,644 Page 2

Art Unit: 1648

#### **DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

### Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Art Unit: 1648

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 8, 10, drawn to isolated purified DNA molecule. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

Group II, claim(s) 4, drawn to purified protein. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

Group III, claim(s) 5, drawn to antibodies. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

Group IV, claim(s) 6, 7, drawn to process for expression of human papillomavirus type 18 in host.

Group V, claim(s) 9, drawn to vaccine for prevention or treatment of human papillomavirus. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

Group VI, claim(s) 11, 12, 15, 16, 17, 20, drawn to virus like particles, vaccine, composition, and method of preventing papillomavirus infection. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

Application/Control Number: 08/913,644

Page 4

Art Unit: 1648

Group VII, claim(s) 13, drawn to method of producing virus like particles.

Group VIII, claim(s) 14, drawn to recombinant papillomavirus protein. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

Group IX, claim(s) 18, drawn to method of producing yeast derived recumbent capsid protein.

Group X, claim(s) 19, drawn to virus like particles. (Please note if this group is selected further select one sequence to be examined on the merits, and amend the claims accordingly, see below for explanation)

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Cole et al (Journal of Molecular Biology, 1987) wherein the reference teaches an isolated and purified DNA molecule which encodes human papillomavirus type 18 or functional derivative (see Figure 1). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2.

Application/Control Number: 08/913,644

Art Unit: 1648

Upon election any one of Group I, II, III, V, VI, or VIII Applicants are additionally required to elect a single Sequence identified by a specific sequence identification number, as indicated above as they apply to group(s). The recited sequences have different structures one from other and the search for the sequences would be unduly burdensome. This requirement is not to be construed as a requirement for an election of species, since each of the sequence(s) recited constitutes an independent and patentably distinct invention.

Page 5

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

8/22/2003

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Application No.: 08/9/3,644
NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

K	1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
X	2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
X	3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
	4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
	5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
	6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
	7. Other:
Αp	pplicant Must Provide:
Ø	An <u>initial</u> or substitute computer readable form (CRF) copy of the "Sequence Listing".
Q/	An <u>initial</u> or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
	A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
For	questions regarding compliance to these requirements, please contact:
For For	Rules Interpretation, call (703) 308-4216 CRF Submission Help, call (703) 308-4212 PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE